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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,333	01/09/2001	Samuel I. Achilefu	MRD-67	5506

26875 7590 05/12/2003

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CINCINNATI, OH 45202

EXAMINER
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JONES, DAMERON

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 05/12/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/757,333

Applicant(s)

ACHILEFU ET AL.

Examiner

D. L. Jones

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,7-15,18 and 19 is/are rejected.
- 7) ☒ Claim(s) 3,6,16,17 and 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### **APPLICANT'S INVENTION**

1. Applicant's invention is directed to compounds, compositions, and uses thereof comprising the formula as set forth in independent claims 1, 4, and 18.

### **RESPONSE TO APPLICANT'S ELECTION**

2. Applicant's election with traverse of Group I directed to compounds, compositions, and uses thereof wherein W5 and X5 are CR1R2 in Paper No. 18, filed 3/6/03, is acknowledged. In addition, acknowledgment of the species wherein W5 and X5 = C(CH<sub>2</sub>OH)<sub>2</sub>; Y5 = (CH)<sub>2</sub>-CONH-Bm; Z5 = (CH<sub>2</sub>)<sub>2</sub>CONH-Dm; A3 = single bond; A3, B3, C3, and D3 = 6-membered carbocyclic ring; a5 = 1; R58 = galactose; R59-R66 = H; Bm = octreotate; and Dm = bombesin. The traversal is on the ground(s) that the restriction is improper because all the claims are directed to the structure designated as formula 3 and all the claimed compounds have the same utility. This is found non-persuasive because (1) while it is noted that the claims are directed to compounds, compositions, and uses thereof comprising formula 3, it is also noted that depending upon the variable definitions assigned to W5 and X5, the core structure changes such that there is no common core from one group of species to another. For example, the core for compounds and composition wherein both W5 and X5 = CR1R2 is very different from a core wherein both W5 and X5 are sulfur. Thus, separate searching and consideration of the prior art is necessary for each group of species since one group of compounds/compositions neither anticipates nor renders obvious the other group. Hence, the Examiner would be required to conduct a burdensome search in order to

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search the full scope of the claims since various searches would be necessary.

Furthermore, just for clarification of the record, it should be noted that each group set forth by the Examiner in the restriction requirement encompasses compounds, compositions, and uses thereof. The restriction requirement is still deemed proper and is therefore made FINAL.

**Note:** The search was expanded over the full scope of Group I. Thus, it should be noted that the search was not expanded to any other of the groups as set forth in the restriction requirement mailed 1/29/03, Paper No. 17.

## **DOUBLE PATENTING REJECTION**

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 2, 4, 5, 7-15, 18, and 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,180,086. Although the conflicting claims are not identical, they are not patentably distinct from each other because both groups of claims are directed to compounds, compositions, and uses thereof having the formula as set forth in claim 1 of the instant invention wherein (a) W5 and X5 are CR1R2 and (b) Y5 and Z5 are (CH2)a-NR3R4 or CH2(CH2OCH2)b-CH2NR3R4. The claims differ in that the claims of the instant invention encompass species wherein Y5 and/or Z5 is selected from the group consisting of a peptide, protein, cell, antibody, antibody fragment, saccharide, glycopeptide, peptidomimetic, drug, drug mimic, hormone, chelating agent, radioactive or non-radioactive metal complex, or an echogenic agent.

#### **CLAIM OBJECTIONS**

5. Claims 3, 6, 16, 17, and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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**COMMENTS/NOTES**

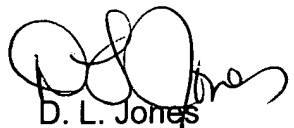
6. It should be noted that no prior art has been cited against Applicant's elected Group I. However, Applicant must address and overcome the double patenting rejection. In particular, the claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious compounds, compositions, and uses thereof encompassed by Group I as set forth above.

Note: Applicant is respectfully requested to cancel the claims directed to the non-elected inventions.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose' Dees can be reached on (703) 308- 4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
D. L. Jones  
Primary Examiner  
Art Unit 1616

May 5, 2003